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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,802	12/09/2003	Arthur Vanmoor	A-9861	4335

20741 7590 09/03/2008
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EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
09/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,802	VANMOOR, ARTHUR	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-11 and 13-15* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse in the reply filed on 15 April 2008 is acknowledged and has been duly made of record.

Status of the Claims

Claims 1-11 and 13-15 are pending in the application. Claims 1-11 and 13-15 are pending for further prosecution on the merits. Claim 12 is cancelled.

Claim 1 is drawn to a method of accelerating the elimination of alcohol in a person in need of such treatment, which comprises the administration of an effective amount of at least one compound represented by formula (I) **X-CH2-CH(OY)q(H) 1-q(CH9NH2+) 1-q COO**$^-$ wherein X represents a carbamoyl group (CONH2) as elected, Y is an acetyl (CHBCO) group as lected, and q is zero or one, provided that when X is a carbamoyl group, q is zero.

Claim 2 depends from claim 1 and is drawn to compound of formula (II), wherein Y is the acetyl group as elected.

Claim 3 depends from claim 1 and is drawn to the compound represented by formula (III).

Claim 4 depends from claim 1 and is drawn to a method wherein compound is administered orally during a period from one hour before alcohol is consumed to one hour after alcohol is consumed.

Claims 5-8 which depend from claim 1 are drawn to a method wherein (1) the compound is administered orally prior to or simultaneously with the consumption of alcohol, (2) the compound is administered rectally as a suppository, (3) the compound is administered in one to five daily doses of 2 to 20 grams each, (4) the total of the compound administered daily is in the range of 2 to 100 grams, respectively.

Claim 9 depends from claim 8 and is drawn to a total of the compound administered daily at 2 to 50 grams.

Claim 10 depends from claim 1 and is drawn to an administered single dose of 30-60 grams.

Claim 11 depends from claim 10 and is drawn to a compound of formula (I) admixed with edible material in a shaped body characterized by a pleasant taste and reduced bulk density.

Claims 13-15 depend from claim 11 and are drawn to a method wherein shaped body is selected from : (1) pretzel as elected, (2) wherein pretzel contains from 10-100 parts by weight of compound represented by formula (I) per 100 parts by weight dry basis of edible materials (3)wherein said edible materials are selected from flour as elected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3, 4-11, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al. (USPN 6, 518, 544 B2) and Yokosuka et al. (USPN 3,717,470) in view of Van Leeuwen et al. (USPN 6,001,878).

Fuchs et al teach [a] stable, refreshing drink for accelerating degradation of alcohol in the body, containing synergistic combination of fructose, taurine, and vitamin B complex component (abstract only).

Fuchs et al. teach if the composition comprises amino acids, in particular L-glutamine and/or L-arginine. Amino acids play an important role in the various metabolic processes of the human body so that the addition of amino acids generally has a positive effect on the alcohol degradation of the body. Especially L-glutamine and L-arginine particularly promote alcohol

degradation, and preferably they are admixed in the following parts by weight, based on a total of 15,000-20,000 parts by weight of dry substance: L-arginine, 20-2,000, in particular 200; L-glutamine, 10-1,000, in particular 100. These amounts yielded optimum alcohol degradation results (col. 5, l/s 3-14).

Fuchs et al. teach 10-10, 000 and in particular 100 parts of L-glutamine in a composition (col. 5, l/s 3-14).

Fuchs et al. teach [that] [t]he inventive refreshing drink of the initially defined type is characterized in that it further comprises a liquid foodstuff in addition to the above-described inventive composition. By dissolving/suspending the composition according to the invention with the liquid foodstuff, a liquid drink for lowering the blood alcohol level is obtained. Primarily, the liquid is water, and both carbonated and non-carbonated water may be used. Yet also any other liquid tolerable for the body may be added, such as, e.g., fruit juices, milk, tea, coffee and the like. Moreover, it is also possible to admix an alcohol-containing drink, e.g. an alcoholic cocktail, so that the alcohol-degrading effect will occur simultaneously with the alcohol consumption (col. 6; l/s 24-36).

Fuchs et al. teach a composition as provided as a dry substance (col. 10, l/s 64-65).

Fuchs et al. does not teach expressly teach the composition in a ready edible material.

However, Yokotsuka et al. glutaminase is added to various foods or beverages containing glutamine. The food or beverage is kept at 10.degree. C to 70 degree. C for at least 0.5 hours so as to hydrolyze the glutamine to glutamic acid and prevent the formation of pyroglutamic acid (abstract only).

Yokotsuka et al. teach an object of the present invention is to provide a process for preparing foods and beverages having an excellent deliciousness by utilizing to advantage such free glutamine in food and beverage materials that had heretofore never been utilized. Another object of the invention is to provide very useful foods and beverages which are so rich in natural flavor that the additional L-glutamic acid becomes quite unnecessary or can be saved to a great extent, the addition of which had conventionally been done during the processing, or either before or after the processing. A further object of the present invention is to provide a means of preparing foods and beverages excellent in flavor by preventing the conversion of glutamine in the raw materials into pyroglutamic acid, the formation of which is considered undesirable for foods and beverages because of its bitter taste and phenolic odor (col. 2, l/s 30-47).

It is noted that applicants elect the shaped body of pretzels and the edible material of flour. However, these limitations hold not patentable weight. Principally, a pretzel made of flour is a food and is fully encompassed by the teachings of Yokotsuka et al. Accordingly, a pretzel as would be apparent to one of skill in the pertinent art could be modified in such a way as to appear as another shaped body or a component of another shaped body (i.e., bread crumbs, sweetened as a form of cookie, shaped into and comprised in a breadstick).

Yokotsuka et al. does not teach protocols of administered dosages of glutamine.

However, Van Leeuwen et al. teach that the invention is specifically directed at the use of glutamine or a glutamine equivalent for preparing a medicinal or nutritional composition for the treatment of diseased states where there is a decreased blood flow to the liver or where there are low arginine plasma levels. These diseased states can be those mentioned above, especially

endotoxemia, systemic inflammation, high plasma arginase level, bacteremia, jaundice, liver transplantation, liver resection, inflammatory bowel disease, or increased cytokine production (col. 1, l/s 39-48).

A glutamine equivalent is understood to be a substance which can be converted to glutamine, such as a glutamine dipeptide or a 2-acylaminoglutaric acid monoarnide. The glutamine or glutamine equivalent in the medicinal or nutritional composition may be supplemented by arginine or an arginine equivalent, e.g. to an amount of 0-50%, especially 1-25% of the combined amounts of glutamine and arginine and their equivalents. The medicinal or nutritional composition preferably contains an amount of glutamine or glutamine equivalent such as to provide a daily glutamine dosage of 0.2-4 g/kg body weight. This means that glutamine or its equivalent is administered in amount of e.g. **10-200 g/day** for a subject having a body weight of 50 kg, or **20-400 g/day** for a subject having a body weight of 100 kg. Below, the levels to be used are given on the basis of an assumed average body weight of 75 kg, but adaptations can be made as necessary (col. 1, l/s 49-65).

The medicinal and nutritional compositions according to the invention are preferably formulated as enteral compositions. The composition may be a complete artificial food, i.e. which does not require additional food, or a food supplement. The further components of a complete food are preferably based on the recommended daily allowances (RDA) as generally accepted; the protein fraction may be based on a protein source rich in glutamine, or its hydrolysates. A supplement may be a glutamine contrate, e.g. obtained by hydrolysis of raw materials rich in glutamine, such as wheat protein. The enteral food may then be obtained by mixing, before use, of the concentrate with a basic food, e.g. according to the RDA. The

composition preferably is liquid composition for oral or cathereterised administration. Preferably the composition is a nutritional composition which also contains carbohydrates, proteins, lipids, and especially fibres, in amounts that are sufficient for meeting a minimum daily nutritional requirement (col. 1, l/s 66-67; col. 2, l/s 1-16).

The invention also concerns novel nutritional compositions suitable for improving liver function, containing, as a daily dosage unit, 12-300 g of glutamine or a glutamine equivalent, together with an amount of carbohydrates, proteins, lipids, vitamins, minerals and vegetable fibres, which is sufficient for meeting a minimum daily nutritional requirement. The nutritional composition preferably contains, as a daily dosage unit, especially 15-300, more preferably 16-150, more in particular 30-100 g of glutamine or a glutamine equivalent. The amount of glutamine or equivalent thereof can also be given with reference to the total weight of the composition. In case of liquid compositions, which are preferred, the amount of glutamine is in particular from 7 to 150 g/l, especially from 15 to 150, more in particular 25 to 75 g/l (col. 2, l/s 17-31).

Where the amount of glutamine is too high to be able to be homogeneously mixed with the other components, it is advantageous to prepare a nutritional composition, wherein at least a part (e.g., greater than or equal to 75%) of the glutamine is in a package form separate of the major part (e.g., greater than or equal to75%) of the composition. The separate packages can then be combined before use. In such a way, stability problems can be overcome (col. 2, l/s 36-42).

Van Leeuwen et al. teach that [t]he combined use of glutamine and alanine for the treatment of alcohol intoxication of the liver [...] (col. 3, l/s 6-7).

Thus, it would be prima facie obvious to one of skill at the time of invention to at once recognize a reasonable expectation of success via the combining and incorporating together the teachings and methods of Fuchs et al. Yokotsuka et al. and Van Leeuwen et al.

In determining the scope and contents of the prior art, Fuchs et al. comprises a scope drawn to an oral preparation in the form of a dry substance (powder) that may be formulated into a beverage. The limitation drawn to a dry substance to the one of skill may also readily be incorporated into a shaped body (i.e., pretzel) comprised with an edible material such as flour. This limitation is not taught by Fuchs et al. but the one of skill would have been inclined to optimize the use based on the limitation in the abstract drawn to a syrup, which is an edible shaped body/material. Further Yokotsuka et al. teach expressly teach the use of glutamine in food. Yokotsuka et al. scope and content of invention is drawn to the stabilization of glutamine in food and methods of maintaining such stability for palatable flavor. Still Further Van Leeuwen et al. teach a scope and content in view of claimed invention that discloses well-established daily requirements for the oral administration of glutamine in variable edible combinations or precursors of edible combinations.

The differences between the prior art and the claims at issue is that Yokotsuka et al. does not disclose glutamine expressly for the treatment of alcoholism or the method of increasing the body's capacity to breakdown alcohol. However, Fuchs et al. and Van Leeuwen et al adequately address and overlap the scope of the claimed invention by teaching glutamine for the use of treating an intoxicated liver via alcohol use and for increasing the body's capacity to breakdown alcohol.

The objective evidence present in the application indicating obviousness is the use via a method of accelerating the elimination of alcohol in a person in need of such treatment. Fuchs et al. adequately teach the obvious elements of claimed invention with exception of foodstuffs and specific dosage requirements. Yokotsuka et al. teach the element of the current invention drawn specifically to the a more stabilized glutamine compound being incorporated in foods. The obviousness of Yokotsuka et al. results resides in the fact that in order to properly address the limitations as disclosed in claim 1, the compound would have to be in a stable formulation in order to have the desired effect in accelerating the elimination of alcohol in a person in need thereof. Van Leeuwen et al. provides further obviousness and motivation to combine with the other references as cited based on the said reference addressing well-established dosing protocols for glutamine for dietary and nutritional intake which adequately encompass/overlap the dosing requirements according to the current invention.

Objection

Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary/supervisor Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624
TEB